IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9011

Bartle, J. February 27, 2013

Maria B. Newcomb ("Ms. Newcomb" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. George A. Newcomb, Ms. Newcomb's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust, Dr. Evans has signed in excess of 322 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated March 13, 2002, Dr. Evans attested in Part II of Ms. Newcomb's Green Form that claimant suffered from moderate mitral regurgitation, mild aortic regurgitation, an abnormal left ventricular end-systolic

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

dimension, and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $628,632.[4]

In July, 2005, the Trust forwarded the claim for review by Jeremy I. Nadelmann, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Nadelmann concluded that there was no reasonable medical basis for the attesting physician's findings that Ms. Newcomb had moderate mitral regurgitation, mild aortic regurgitation, an abnormal left ventricular end-systolic dimension, or a reduced ejection fraction in the range of 50% to 60%. With respect to claimant's level of mitral regurgitation, Dr. Nadelmann explained that "[t]here is no [mitral regurgitation] shown by color Doppler. The echocardiogram does show trace [mitral regurgitation] which is demonstrated by pulsed Doppler in the 4-chamber view." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. With respect to claimant's level of aortic regurgitation, Dr. Nadelmann explained, "There is only trace [aortic

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4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). An abnormal left ventricular end-systolic dimension and a reduced ejection fraction are each one of the complicating factors needed to qualify for a Level II claim.

insufficiency] shown by color Doppler. The technical quality of the [echocardiogram] is only adequate. By pulsed Doppler, [aortic insufficiency] is demonstrated, however it cannot be quantified." Under the definition set forth in the Settlement Agreement, mild or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable) is equal to or greater than ten percent (10%) of the left ventricular outflow tract height ("LVOTH"). Id. With respect to claimant's left ventricular end-systolic dimension, Dr. Nadelmann explained, "The [patient] has normal [left ventricular] end systolic dimensions by parasternal views. The measurements done by the attesting cardiologist are done in the parasternal short axis views and are off axis." The Settlement Agreement defines an abnormal left ventricular end-systolic dimension as "≥ 45 mm by M-mode or 2-D Echocardiogram." Id. § IV.B.2.c.(2)(b)iii. With respect to claimant's ejection fraction, Dr. Nadelmann explained, "The [patient] has normal [left ventricular shortening fraction] with an [ejection fraction]=65%. There are no regional wall motion abnormalities. In addition, the attesting cardiologist reports normal [left ventricular shortening fraction] in his report."

Based on Dr. Nadelmann's findings, the Trust issued a post-audit determination denying Ms. Newcomb's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit

Rules"), claimant contested this adverse determination.[5] In contest, Ms. Newcomb abandoned her claim for Level II Matrix Benefits. She argued, however, that she was entitled to Fund A Benefits[6] because there was a reasonable medical basis for her attesting physician's representation that she suffered from mild aortic regurgitation.[7] In support of her claim, she submitted a new affidavit from Dr. Evans. Although Dr. Evans changed his opinion with respect to claimant's level of mitral regurgitation, he confirmed his finding of mild aortic regurgitation with a JH/LVOTH ratio of 12%.[8]

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5. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Newcomb's claim.

6. Specifically, Ms. Newcomb asserted that she was entitled to a $6,000 cash payment pursuant to Section IV.A.1.c. of the Settlement Agreement.

7. To receive Fund A Benefits pursuant to Section IV.A.1.c. of the Settlement Agreement, a class member must be diagnosed as FDA Positive by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement § IV.A.1.c. FDA Positive is defined as "mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve." Id. § I.22.

8. Claimant also contested the Trust's determination that Ms. Newcomb had only trace, rather than mild, mitral regurgitation. As a finding of mild mitral regurgitation will not entitle her to Fund A Benefits, we will not reach that issue.

The Trust then issued a final post-audit determination, again denying Ms. Newcomb's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Newcomb's claim should be paid. On January 19, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5953 (Jan. 19, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 6, 2006, and claimant submitted a sur-reply on April 27, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that she had mild aortic regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Newcomb repeats the arguments she made in contest. Claimant also argues that the concept of inter-reader variability accounts for the differences between the opinions provided by claimant's attesting physician and the auditing cardiologist. According to claimant, there is an "absolute" inter-reader variability of between 10% and 15% when evaluating aortic regurgitation. Thus, Ms. Newcomb contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the JH/LVOTH ratio for a claimant is 10%, a

finding of a 25% JH/LVOTH by an attesting physician is medically reasonable.

In response, the Trust argues that the concept of inter-reader variability does not account for the difference in the findings of Dr. Evans and Dr. Nadelmann because Dr. Nadelmann found there is no reasonable medical basis for the representation of mild aortic regurgitation by Dr. Evans. According to the Trust, the reasonable medical basis standard employed by the Trust's auditing cardiologists is "designed to account for reasonable variation in different cardiologist's findings."

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Newcomb had mild aortic regurgitation.[10] Specifically, Dr. Vigilante determined that:

> This study was not conducted in a manner consistent with medical standards. This echocardiographic study was incomplete as there was no documentation of an apical two chamber view. In addition, there was significantly increased color gain noted during color Doppler evaluation in the apical four chamber view....
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> ....
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> The aortic valve was minimally thickened and opened and closed normally. There was no evidence of calcification. The parasternal

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10. Dr. Vigilante also determined Ms. Newcomb's "echocardiogram of March 13, 2002 did not demonstrate mitral regurgitation on color Doppler evaluation." As we noted previously, a finding of mild mitral regurgitation will not entitle her to Fund A Benefits, and we will not reach this issue.

> long-axis view was available for the determination of aortic regurgitation. Visually, only trace aortic regurgitation was noted in the parasternal long-axis view. I digitized those cardiac cycles in the parasternal long-axis view in which the aortic regurgitant jet was best visualized. I then measured the JH and LVOTH with electronic calipers. I determined that the largest representative JH was 0.15 cm. I determined that the LVOTH was 2.2 cm. Therefore, the largest representative JH/LVOTH ratio was 7%. This ratio did not reach 10% in any cardiac cycle. Therefore, only trace aortic regurgitation could be diagnosed in the parasternal long-axis view on this study. The sonographer did not determine the JH on this study. The sonographer determined an LVOTH of 2.17 cm, which is similar to my measurement of 2.2 cm.
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> ....
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> In response to Question 2, there is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.b. That is, the echocardiogram of March 13, 2002 demonstrated only trace aortic regurgitation with comments as above. An echocardiographer could not reasonably conclude that mild aortic regurgitation was present on this study when making quantitative measurements of the aortic regurgitant jet in the parasternal long-axis view even taking into account inter-reader variability.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately refute the conclusions of the auditing cardiologist or the Technical Advisor. Dr. Nadelmann reviewed claimant's echocardiogram and determined "[t]here is only trace [aortic insufficiency] shown by color Doppler. The technical quality of the echo is only adequate. By pulsed Doppler, [aortic

insufficiency] is demonstrated, however it cannot be quantified." Dr. Vigilante also reviewed claimant's echocardiogram and determined that the largest representative JH/LVOTH ratio was 7%.[11] Neither claimant nor Dr. Evans identified any particular error in the conclusions of the auditing cardiologist and Technical Advisor. Mere disagreement with the auditing cardiologist and Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Moreover, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Newcomb had mild aortic regurgitation is misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist and the Technical Advisor determined claimant's echocardiogram demonstrated only trace aortic regurgitation and Dr. Vigilante measured claimant's JH/LVOTH ratio as less than 10%. Adopting claimant's argument that inter-reader variability expands the range of mild aortic regurgitation by ±15% would allow a claimant to recover benefits with a JH/LVOTH ratio well below the

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11. Despite an opportunity to do so, Claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

threshold established by the Settlement Agreement and render meaningless this critical provision.[12]

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had mild aortic regurgitation. Therefore, we will affirm the Trust's denial of Ms. Newcomb's claim for Matrix Benefits and the related derivative claim submitted by her spouse. We also will affirm the Trust's denial of Ms. Newcomb's claim for Fund A Benefits.

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12. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement that "[a]n echocardiographer could not reasonably conclude that mild aortic regurgitation was present on this study when making quantitative measurements of the aortic regurgitant jet in the parasternal long-axis view even taking into account inter-reader variability."